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NCIC HPV
Sent by: Mary-Beth
Weaver

02/27/2003 02:24 PM

To: NCIC HPV, Jodi Burgess/DC/USEPA/US@EPA
cc:
cc:
Subject: Environmental Defense comments on Nitroglycerin, CAS 55-63-0



Richard_Denison@environmentaldefense.org on 02/26/2003 03:53:00 PM

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Subject: Environmental Defense comments on Nitroglycerin, CAS 55-63-0

(Submitted via Internet 2/26/2003 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and kordoskie@socma.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Nitroglycerin (CASRN 55-63-0).

The Synthetic Chemical Manufacturers Association's (SOCMA) U.S. Nitroglycerin Producer's Association Consortium (USNPAC) comprised of Alliant Techsystems, Inc., Copperhead Chemical Company, Inc., Dyno Nobel, Inc., and St. Marks Powder, Inc., has submitted a Robust Summary/Test Plan for nitroglycerin under the HPV Challenge Program. With the exception of inhalation studies, data to support the required SIDS elements are quite adequate. We agree that, as pointed out in the letter of submission, inhalation studies have not and should not be conducted, because of safety concerns.

The Robust Summary and Test Plan submitted for nitroglycerin are somewhat unique. The Robust Summary actually consists of forty-one small robust summaries that individually address each of the SIDS data elements and provide supporting data and some discussion. This approach, while acceptable, does result in a great deal of redundant introductory material, and the level of detail describing methods used and results obtained often exceeds that normally contained in a Robust Summary. As a result, this Robust Summary is a much larger document than would necessary. However, it does adequately describe the data and the quality of the data for each SIDS element. An additional optional SIDS element, "Experiences with Human Exposure", unfortunately is not addressed even though considerable data are available. Given that there is significant occupational exposure to nitroglycerin, and that millions of people are exposed to it in drug form, we feel it would be appropriate and of interest to the public if this optional element were addressed.

The Test Plan is less acceptable, in that it consists only of a matrix of the required SIDS data elements and minimal inclusion of data that address those elements. The Test Plan contains no discussion of the chemical/physical properties, ecotoxicity, animal toxicity or genotoxicity of nitroglycerin and no mention at all of its effects on humans. The Test Plan also fails to provide any references for the limited data that are presented in the matrix. Descriptions of the data and references are presented in the Robust Summary, but we feel the adequacy of the data on

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nitroglycerin might be more effectively illustrated and communicated to the public and informed professionals if the Test Plan contained a concise summary of the wealth of data provided in the Robust Summary.

Finally, as with the Robust Summary, we feel considerable value would be added to this submission if human exposure, both occupational and medicinal, were addressed.

Thank you for this opportunity to comment.

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